

Response to Office Action
Docket No. 020.0254.US.CON

Amendments to the Specification

On page 3, lines 3-13, please replace the existing paragraph with the following substitute paragraph :

Alternatively, these telemetered signals can be remotely collected and
5 analyzed using an automated patient care system. One such system is described in a
related, commonly owned U.S. Patent application, ~~Serial No. 09/324,894, filed June~~
~~3, 1999, pending, No. 6,312,378, issued November 6, 2001,~~ the disclosure of which
is incorporated herein by reference. A medical device adapted to be implanted in an
individual patient records telemetered signals that are then retrieved on a regular,
10 periodic basis using an interrogator or similar interfacing device. The telemetered
signals are downloaded via an internetwork onto a network server on a regular, e.g.,
daily, basis and stored as sets of collected measures in a database along with other
patient care records. The information is then analyzed in an automated fashion and
feedback, which includes a patient status indicator, is provided to the patient.

15 On page 8, line 22 through page 9, line 13, please replace the existing paragraph
with the following substitute paragraph:

FIGURE 1 is a block diagram showing an automated collection and analysis
patient care system 10 for providing diagnosis and monitoring of congestive heart
failure in accordance with the present invention. An exemplary automated
20 collection and analysis patient care system suitable for use with the present
invention is disclosed in the related, commonly-owned U.S. Patent application,
~~Serial No. 09/324,894, pending, filed June 3, 1999, No. 6,312,378, issued~~
~~November 6, 2001,~~ the disclosure of which is incorporated herein by reference.
Preferably, an individual patient 11 is a recipient of an implantable medical device
25 12, such as, by way of example, an IPG, cardiovascular or heart failure monitor, or
therapeutic device, with a set of leads extending into his or her heart and electrodes
implanted throughout the cardiopulmonary system. Alternatively, an external

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monitoring or therapeutic medical device 26, a subcutaneous monitor or device inserted into other organs, a cutaneous monitor, or even a manual physiological measurement device, such as an electrocardiogram or heart rate monitor, could be used. The implantable medical device 12 and external medical device 26 include
5 circuitry for recording into a short-term, volatile memory telemetered signals stored for later retrieval, which become part of a set of device and derived measures, such as described below, by way of example, with reference to FIGURE 2. Exemplary implantable medical devices suitable for use in the present invention include the Discovery line of pacemakers, manufactured by Guidant Corporation, Indianapolis,
10 Indiana, and the Gem line of ICDs, manufactured by Medtronic Corporation, Minneapolis, Minnesota.

On page 9, line 14 through page 10, line 3, please replace the existing paragraph with the following substitute paragraph:

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The telemetered signals stored in the implantable medical device 12 are preferably retrieved upon the completion of an initial observation period and subsequently thereafter on a continuous, periodic (daily) basis, such as described in the related, commonly-owned U.S. Patent application, ~~Serial No. 09/361,332,~~
20 ~~pending, filed July 26, 1999, No. 6,221,011, issued April 24, 2001,~~ the disclosure of which is incorporated herein by reference. A programmer 14, personal computer 18, or similar device for communicating with an implantable medical device 12 can be used to retrieve the telemetered signals. A magnetized reed switch (not shown) within the implantable medical device 12 closes in response to the placement of a
25 wand 13 over the site of the implantable medical device 12. The programmer 14 sends programming or interrogating instructions to and retrieves stored telemetered signals from the implantable medical device 12 via RF signals exchanged through the wand 13. Similar communication means are used for accessing the external medical device 26. Once downloaded, the telemetered signals are sent via an
30 internetwork 15, such as the Internet, to a server system 16 which periodically receives and stores the telemetered signals as device measures in patient care

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records 23 in a database 17, as further described below, by way of example, with reference to FIGURES 2 and 3. An exemplary programmer 14 suitable for use in the present invention is the Model 2901 Programmer Recorder Monitor, manufactured by Guidant Corporation, Indianapolis, Indiana.

- 5 On page 12, line 20 through page 13, line 2, please replace the existing paragraph with the following substitute paragraph:

The device and derived measures sets 24a, 24b (shown in FIGURE 1), along with quality of life and symptom measures sets 25a, 25b, as further described below with reference to FIGURE 3, are continuously and periodically received by the
10 server system 16 as part of the on-going patient care monitoring and analysis function. These regularly collected data sets are collectively categorized as the monitoring sets 27 (shown in FIGURE 1). In addition, select device and derived measures sets 24a and quality of life and symptom measures sets 25a can be designated as a reference baseline 26 at the outset of patient care to improve the
15 accuracy and meaningfulness of the serial monitoring sets 27. Select patient information is collected, recorded, and derived during an initial period of observation or patient care, such as described in the related, commonly-owned U.S. Patent application, Serial No. 09/361,332, pending, filed July 26, 1999, No. 6,221,011, issued April 24, 2001, the disclosure of which is incorporated herein by
20 reference.

On page 20, line 13 through page 21, line 10, please replace the existing paragraph with the following substitute paragraph:

Thus, if other disorders or diseases are being cross-referenced and diagnosed (block 141), their status is determined (block 142). In the described embodiment,
25 the operations of ordering and prioritizing multiple near-simultaneous disorders (box 151) by the testing of threshold limits and analysis in a manner similar to congestive heart failure as described above, preferably in parallel to the present determination, is described in the related, commonly-owned U.S. Patent application,

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Serial No. , entitled ~~"Automated Collection And Analysis Patient Care System And Method For Ordering And Prioritizing Multiple Health Disorders To Identify An Index Disorder,"~~ pending, filed November 16, 1999, No. 6,440,066, issued August 27, 2002, the disclosure of which is incorporated herein by reference. If

5 congestive heart failure is due to an obvious inciting cause, i.e., secondary congestive heart failure, (block 143), an appropriate treatment regimen for congestive heart failure as exacerbated by other disorders is adopted that includes treatment of secondary disorders, e.g., myocardial ischemia, respiratory insufficiency, atrial fibrillation, and so forth (block 144) and a suitable patient status

10 indicator 127 for congestive heart failure is provided (block 146) to the patient. Suitable devices and approaches to diagnosing and treating myocardial infarction, respiratory distress and atrial fibrillation are described in related, commonly-owned U.S. Patent applications, Serial No. , entitled ~~"Automated Collection And~~

15 ~~Analysis Patient Care System And Method For Diagnosing And Monitoring Myocardial Ischemia And Outcomes Thereof,"~~ pending, filed November 16, 1999; Serial No. , entitled ~~"Automated Collection And Analysis Patient Care System And Method For Diagnosing And Monitoring Respiratory Insufficiency And~~

20 ~~Outcomes Thereof,"~~ pending, filed November 16, 1999; and Serial No. , entitled ~~"Automated Collection And Analysis Patient Care System And Method For~~

~~Diagnosing And Monitoring The Outcomes Of Atrial Fibrillation"~~ pending, filed November 16, 1999, No. 6,368,284, issued April 9, 2002; U.S. Patent No. 6,398,728, issued June 4, 2002; and U.S. Patent No. 6,411,840, issued June 25, 2002, the disclosures of which are incorporated herein by reference.

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